Musculoskeletal Clinical
Regulatory Advisers, LLC

THE 2010 MCRA FACT BOOK

GREATER THAN 100 FACTS ON:

- CLINICAL TRIALS
- REGULATORY
- REIMBURSEMENT

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PREFACE

In 2010, the worldwide orthopedic industry is estimated to be an approximately $40 billion dollar market in end user revenues of orthopedic technologies. Orthopedic technologies are constantly evolving in all ways, including:

- Materials (Biologics, Evolutionary Metals & Plastics, & Antimicrobial Coatings)
- Clinical Trials (Electronic Data Capturing & Different Statistical Methodologies)
- Sales and Marketing (Physician-Owned Distributorships & Direct-to-Consumer Marketing)

We believe these evolutions and added complexities have made it more difficult for key regulatory (FDA), reimbursement (Medicare, Medicaid, and private payors), and compliance (Office of Inspector General, FDA, Department of Justice, Center of Medicaid Service, among others) constituents to determine and create gold standards to which then can be regulated.

The United States continues to enjoy more than 50% of the worldwide market for orthopedic technologies due to excellent pricing (usually 2 times greater than the rest of the world), demographic growth due to the baby boomers, U.S. patients requiring the best technology and U.S. surgeons sub-specializing. These facts alone motivate most companies in the orthopedic space to enter the U.S. marketplace. At the same time technology commercialization in the U.S. is taking longer and costing more. This is due to:

- Clinical Trial Risks – Slowing enrollment, surgeon financial relationships, slowing IRB approvals, and accurately reimbursing institutions and surgeons their "fair market value" for studying novel technologies.
- Introducing Earlier Stage Technologies – Younger patients often desire solutions to be treated earlier, to remove less tissue, and to help the body heal itself. However, to effectively compare earlier stage technologies in the clinical setting to later stage "gold standards" is often inappropriate, although usually required by the FDA.
- Clinical Data – Throughout the entire world (including the U.S.), clinical data is becoming necessary for regulatory approval --- even for technologies with near identical peers already commercialized without clinical data.
- Proof of Superiority – Reimbursement constituents no longer agree with the FDA that non-inferiority is enough.

Within the intricacies of initiating and conducting clinical trials, sponsoring companies all share the same conflict: marketing departments often prefer clinical studies that can be conducted quickly while surgeon users and regulatory agencies desire long term clinical data. Therefore, it is becoming more and more evident that regulatory, reimbursement and compliance needs to be integrated into the design and development of clinical trials. In the end, a product supported by quality clinical outcomes will best be positioned for sale in the market if company executives incorporate key reimbursement drivers within the study and throughout the execution of the clinical trial.

Simply put, the day of developing a new product without a comprehensive plan, as well as the day of a "handshake agreement" over an expensive dinner is over. We see 2010 the beginning of a new era. This new era in orthopedics requires companies to invest more throughout the entire commercialization process, as well as after. With these increases in capital investment expertise is becoming more crucial in avoiding mistakes or inaccuracies that potentially could cost companies up to $100 million annually. While there will be several years of transition, ultimately everyone will benefit as doctors, hospitals, and industry become comfortable with the safety and efficacy of new technology as well as the required transparency.

2010 MCRA FACT BOOK

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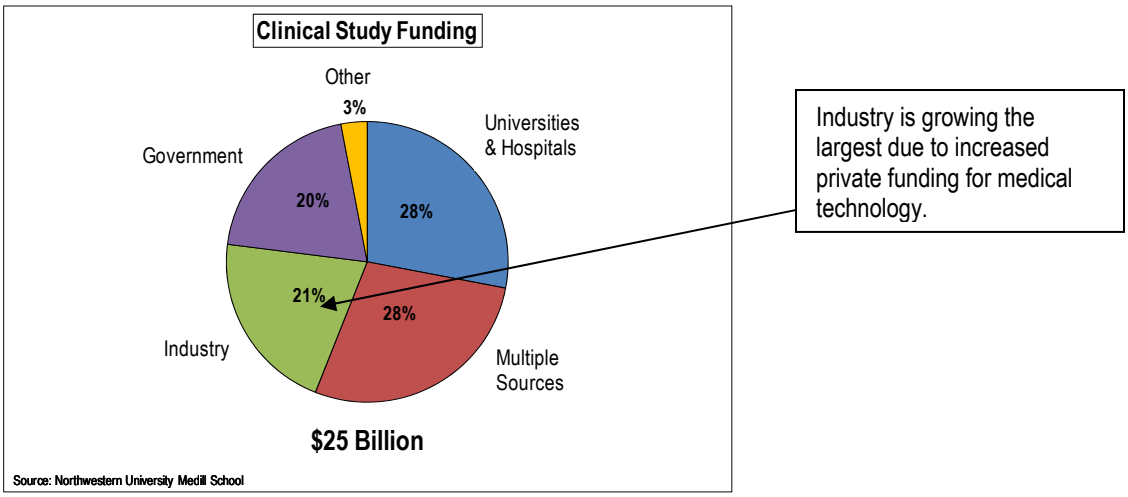
CLINICAL TRIAL FACTS

Overview

1. <1% of the U.S. population (~2.3 million people) participate in approximately 80,000 total clinical trials every year. [19, 46]
2. 70-75% (60,000 of the 80,000) U.S. clinical trials are performed in the private sector relative to the traditional hospital or university. [4, 46]



3. ~3,000 medical device clinical studies are conducted annually. [2]
4. ~1/3 of registered clinical trials in 2009 are conducted exclusively outside the U.S. and over half of all study sites are now outside the U.S. [45]
5. >50% Asia-Pacific clinical trial growth since 2005 (China growing at a 21% CAGR in the last 5 years). [5, 31]

Fast Fact:

CROs provide a wide range of clinical development services to research sponsors, including consultation with study design, investigator recruitment, study monitoring, and data analysis.

6. 58% of clinical trials are currently conducted by electronic data capture (EDC) versus 13% in 2001, growing at a CAGR of 14.7% (>$3.1 billion for 2006-2011). [1, 8]
7. ~75% of people who would consider getting involved in clinical research do not know where studies are conducted or how to evaluate them. [6, 7]
8. >650 Contract Research Organizations (CROs) in the U.S. (~42% growth since 2005 with a total of 269). [43]
9. $17.8 billion CRO market in 2007 compared to $7 billion in 2001, with an estimated industry growth rate of15% annually. [21, 44]

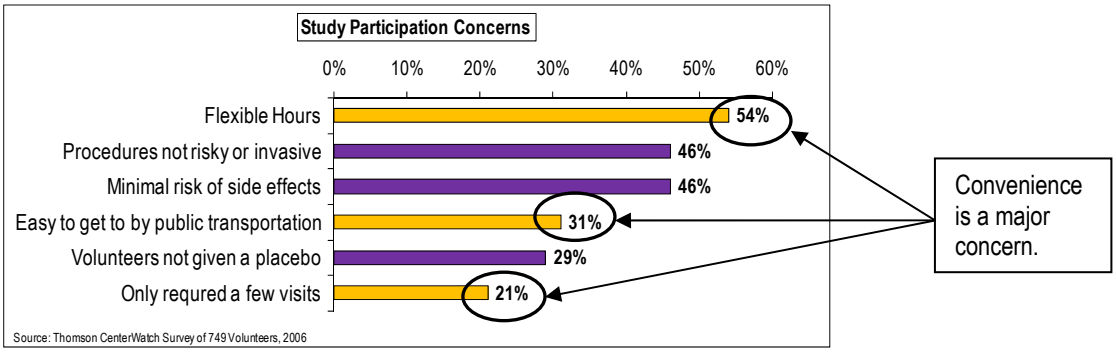
Clinical Trial Enrollment

1. >$500 million is the annual media spending on patient recruitment (>100% increase since 2001), with a growth rate of 34% per year. [13]
2. ~90% of the time, many clinical studies miss deadlines due to slow patient enrollment, which is one of the leading causes of delays in clinical trials. [20]
3. 30% of clinical trial sites fail to enroll a single patient. [15]
4. 1 out of 20 patients who respond to clinical trial recruitment promotions actually enroll in a study. [15]

Fast Fact:

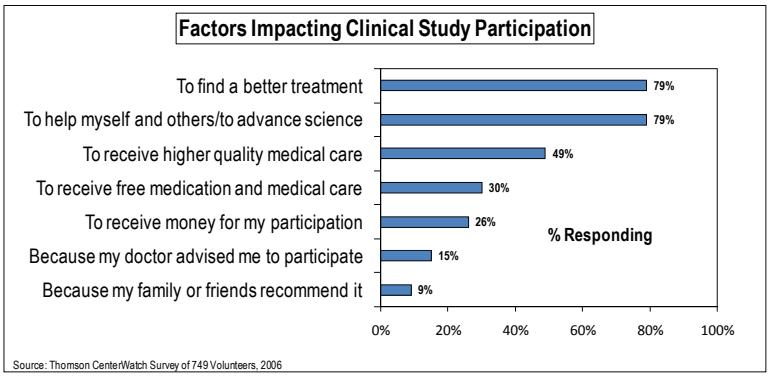
#1 reason physicians do not refer their patients into trials is: *Lack of information on treatments or new investigational drugs.*

5. 60% of physicians have referred patients to clinical trials. [9]
6. Patient enrollment may last 3 to 4 years. [17]
7. At least 6 months of a clinical trial timeline are reserved for trial initiation. [17]
8. 1 out of every 4 (73.2%) volunteers stick with a study until its completion. [7]
9. #1 patient concern in clinical trials participation is convenience relating to flexible hours, not safety. [9]



Clinical Trial Participants

1. 92% of clinical trial participants rated their experiences as either good or very good. [9]
2. 91% of clinical trial participants said they are likely to do so again. [9]
3. 87% of clinical trial participants said they would refer a family member or friend to participate in a clinical trial. [9]
4. 30% of clinical trial participants report that they first learned about a clinical trial from their primary/specialty health care provider. [16, 46]



5. 70% of clinical trial participants report that they first learned about a clinical trial from media or the internet. [16, 46]
6. ~108,000 individuals enter into clinical treatment trials each year sponsored by the National Institutes of Health (NIH). [10]
7. ~10% of eligible people in the United States who suffer from severe and chronic illnesses participate in clinical trials. [3]

Clinical Trial Spending

1. ~$100 million is spent annually by the medical device industry on clinical grants. [2]
2. >$4 billion was paid to clinical study investigators in 2002. [11]
3. 28% of the Med Tech industry R&D spending are from small firms with <100 employees. [23]
4. ~343% of small company revenue was spent on R&D in 2002. [24]

5. ~$20 of the $5,000 (<0.5%) spent per year on health care by an average American is invested in R&D. [46]
6. Investment in R&D more than doubled during the 1990s and now stands at nearly 12% of sales, more than 4x the average for manufacturers. [23]

Musculoskeletal Pharma/Biologic Facts

Fast Fact:

Arthritis is a more frequent cause of activity limitation than diabetes, cancer or heart disease.

1. #1 most common cause of physical disability and severe long-term pain in the U.S. are musculoskeletal related conditions. [53]
2. #1 reason for doctor visits in the U.S. is musculoskeletal impairment. [54]
3. #1 musculoskeletal impairment in the U.S. is back and spinal injuries. [55]
4. ~1% of people worldwide and ~1.3 million people in the U.S. are believed to have rheumatoid arthritis. [52]
5. $936 million is the average cost to bring a rheumatoid arthritis drug to market. [12, 46]
6. 15.3 years is the time it took researchers to develop a new drug in the 1990s, almost double the time it took in the 1960s (8.1 years). [46]

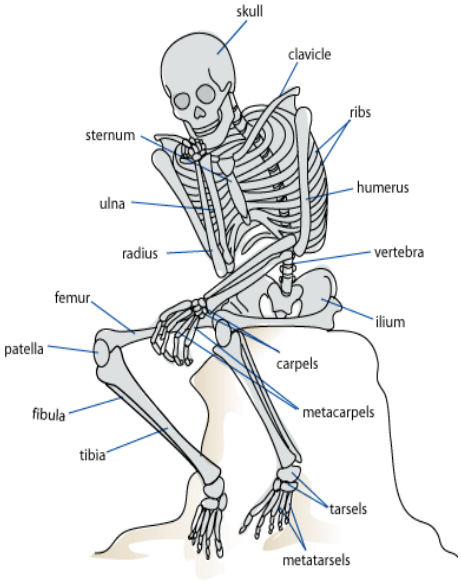


Figure 1: The Science Creative Quarterly

7. ~ 1 in 50 drugs that enter pre-clinical testing prove safe and effective enough to be tested on people. [46]
8. ~70% of new medical treatments pass Phase I testing stage. [11, 47]
9. 70% to 90% of drugs that enter Phase III studies successfully complete this phase of testing. [47]
10. For every 10,000 molecules screened, an average of 250 enter pre-clinical testing, 10 make it through clinical trials, and only 1 is approved. [46]
11. ~10 years of pre-clinical study is conducted in test tubes and laboratory mice to reach the point where treatment might be tested for its safety and effectiveness in humans. [7, 11]

Other Clinical Trial Facts

Fast Fact:

Depending on the extent of the research question, IRB-approval can delay the implementation of your research trial for years.

1. ~$24 billion was the national spending on U.S. clinical trials in 2005, and is estimated to rise to $32.1 billion in 2011. [14]
2. 60-150 days for contract, budget and IRB approval required by academic centers. [2]
3. 30-60 days for contract, budget and IRB approval required by private centers. [2]
4. 7-28 days for contract, budget and IRB approval required by private-practice physicians. [2]
5. 60% of clinical studies performed by investigators were not affiliated with academic centers. [42]
6. ~17% more errors shown on case report forms from academic clinical centers than private institutions. [2]
7. Academic centers consider private research centers as their biggest competitors for conducting clinical research. [2]

REGULATORY FACTS

Overview

1. >1,700 types of medical devices are regulated by the FDA. [25]
2. >23,000 manufacturers are regulated by the FDA. [25]

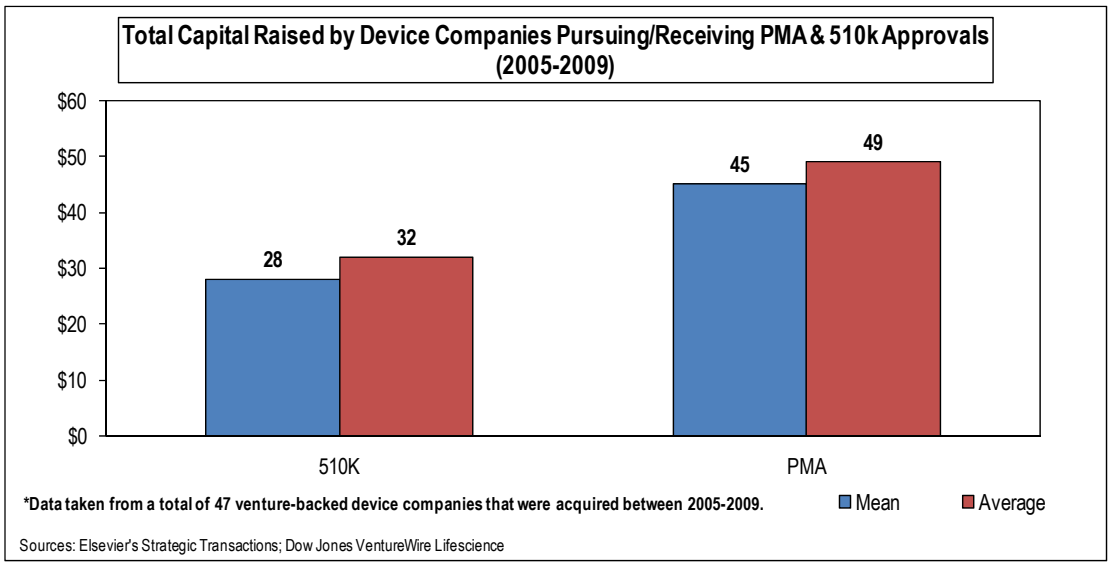
Fast Fact:

Much of the innovation in orthopedics takes place abroad due to more lax regulations.

3. >500,000 medical device models are regulated by the FDA. [25]
4. Regulation has added ~2 years and up to $20 million to the cost of developing and launching a medical product in the US market. [26]
5. 356 days is the average review time for approval of a new medical device in the U.S. in 2004. [27]
6. 50-75 draft and final guidance documents are published each year by the FDA. [28]
7. ~2x as likely to get approved after the initial review process for medical devices developed in areas with existing FDA guidance documents. [28]

510(k) Applications

1. $32 million is the average total capital raised by the venture-backed device companies pursuing/receiving 510(k) approvals. [18]



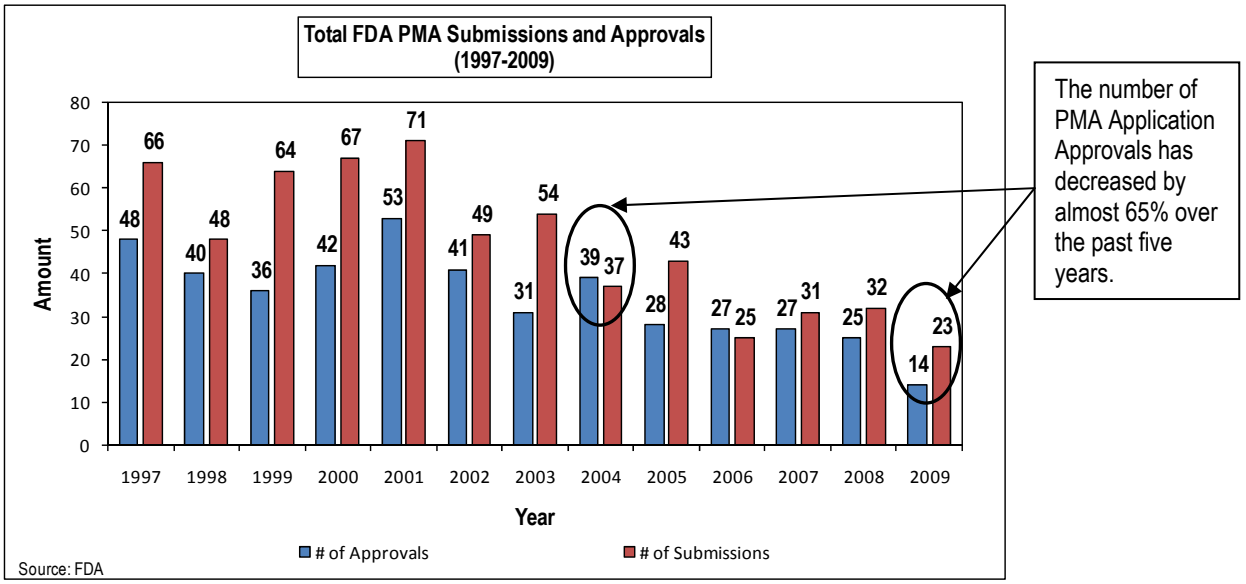
2. ~4,000 510(k) applications claiming substantial equivalence are received by the FDA every year. [25]
3. ~2,500 510(k) clearances is the annual rate per year for the past 5 years. [18]
4. ~10% of 510(k)s require clinical trials. [30]
5. <100 days is the average review time for 510(k) applications for "substantially equivalent" devices. [24]

Fast Fact:

An investigational device exemption (IDE) allows the investigational device to be used in a clinical study in order to collect safety and effectiveness data required to support a PMA application or a 510(k) submission to FDA.

Investigational Device Exemption & Premarket Approval Applications

1. ~$1.5 million is spent on grants by manufacturers to test a single Investigational Device Exemption (IDE). [2]
2. ~250 new IDE clinical trials occur each year. [10]
3. ~80 IDEs are approved each year. [2]
4. 96% of the 1,600 ongoing IDE trials have been placed in category B and 4% in category A. [1]
5. $49 million is the average total capital raised by the venture-backed device companies pursuing/receiving Premarket Approval (PMA) approvals. [18]
6. >250 days is the review time for PMA applications for truly novel devices. [24]
7. <100 PMAs are received by the FDA every year. [25]
8. ~30 PMAs are approved each year. [2]
9. 14 original PMAs (not supplemental) were approved by the FDA through October 2009, the lowest number in 5 years over the same time-period due to tougher standards. [18]
10. 23 filings for new PMA devices were received by the FDA through October 2009, the lowest number in 5 years over the same time-period. [18]



11. >600 filings for supplemental approvals for PMA devices already approved were received by the FDA through October 2009, the highest number in 5 years over the same time-period. [18]

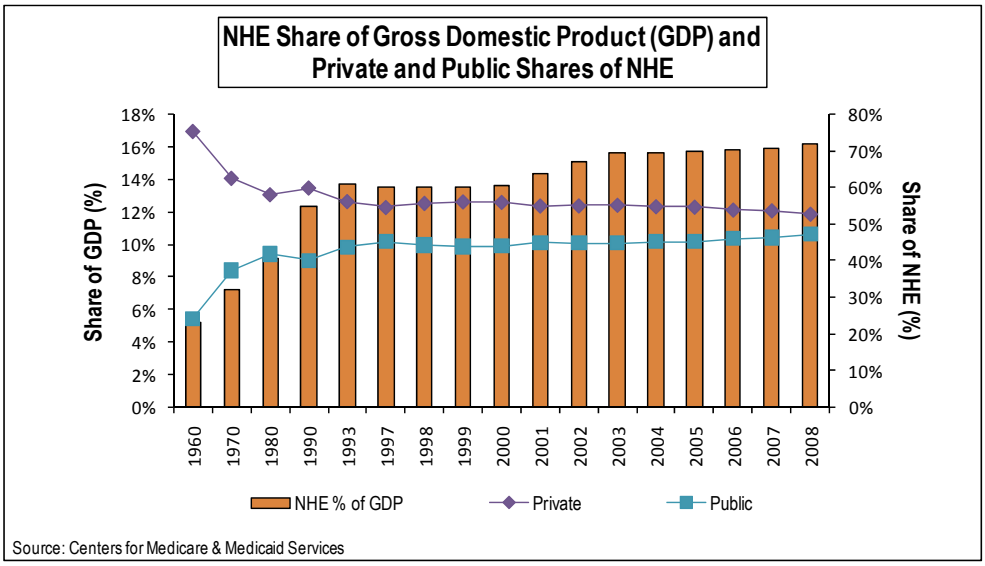
REIMBURSEMENT FACTS

National HealthCare Spending

Fast Fact:

Health-care spending is insulated from the immediate impact of a downturn in the economy; however, the 2008 recession has exerted considerable influence on the health-care sector.

1. ~$2.3 trillion ($7,681 per person) is the overall healthcare costs for the United States in 2008. [22]
2. >16% is the U.S. healthcare spending as a percentage of GDP. [22, 34]
3. Private spending exceeds government health expenditure in the US. [34]
4. Consumers are spending more on healthcare as a percentage of total expenditures. [34]



5. ~36% is the share of federal revenue that funded health care in the U.S. in 2008, compared with 28% in 2007 and 16.3% in 1966. [22, 34]
6. 2.8% increase in out-of-pocket spending for health-care services in 2008, compared with 6% in 2007 due to the impacts of the economic recession. [22]
7. 4.5% increase in spending on hospital care in 2008 ($718.4 billion), the slowest increase since 1998, while the rate of increase was 5.9% in 2007. [22]
8. 5% increase in spending for physician and clinical services in 2008 ($496.2 billion), the slowest rate of growth since 1996, while the rate of growth was 5.8% in 2007. [22]
9. 3.2% increase in retail prescription drug spending ($234.1 billion) in 2008, continuing a slowing trend that began in 2000. [22]
10. 4.6% increase in spending on nursing home care in 2008 ($138.4 billion), compared with a 5.8% increase in 2007. [22]

Reimbursement

Fast Fact:

The procedures for biologics and tissue technologies are not standardized, leading to companies with innovative technologies having a difficult time with the reimbursement process.

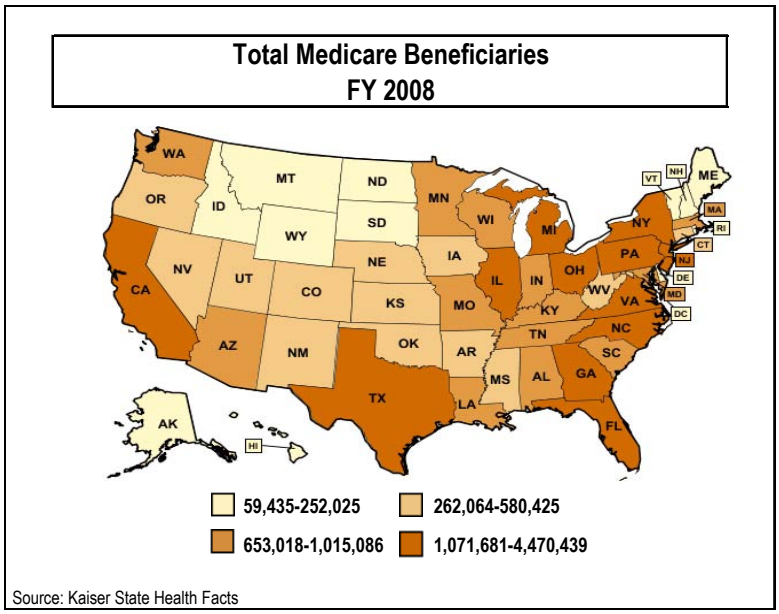
1. 44% of Medical Technology companies indicated that the length of time it takes to secure coverage had significantly hindered their ability to bring an innovative new technology to market. [32]
2. ~50% of Med Tech companies identified inadequate payment levels as the single greatest reimbursement-related hurdle. [32]
3. 94% of FDA IDE products are eligible for reimbursement. [29]
4. ~70% of a hospital's reimbursement is absorbed by the cost of the actual implant for a Medicare patient. [33]
5. From 1992-2007, implant cost per procedure for hip and knee replacement surgery increased at an average annual rate of 3.3%. [48]
6. 0.4% was the decline in the cost per hip/knee implant procedure in 2007-2008. [48]
7. $8,535 is the cost per inpatient stay in 2005, which has increased at a CAGR of 5.2% from 2001 to 2005. [35]

Medicare/Medicaid

1. For 37 million Americans ages 65 and up and 7 million persons with disabilities, medical expenses are paid for by Medicare. [39]
2. ~100% expected increase in enrollment under Medicare (78 million Americans) by 2030 and there was ~100% increase (45 million Americans) in 2008 over the last 35 years. [50]

Fast Fact:

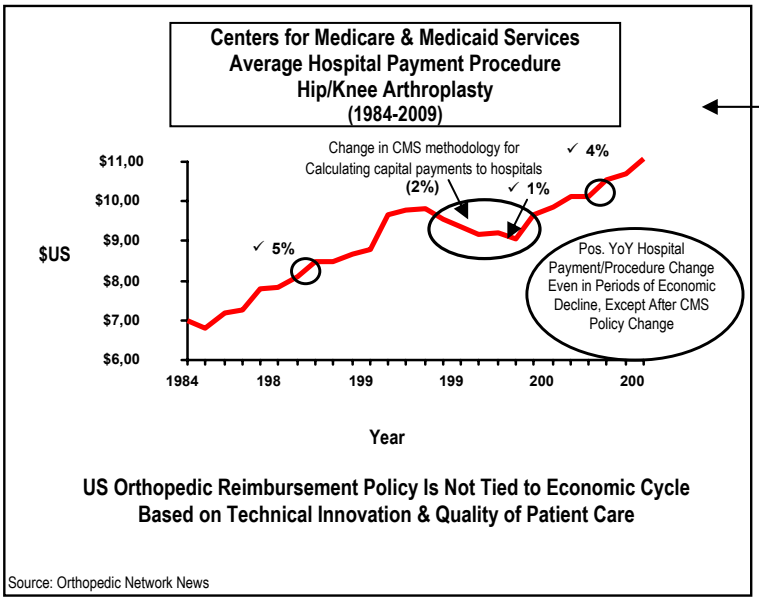
Part A of Medicare is funded primarily by payroll taxes on wages and self-employment income. Parts B and D is financed by monthly premiums, usually deducted from Social Security benefits, as well as by income taxes paid.



Source: Kaiser State Health Facts

3. ~200% increase between 1985 and 2006 in the number of Medicaid recipients (57.7 million total recipients). [51]
4. 3.2% is the percentage of total Medicare expenditures over GDP in 2007, which will grow to 4.4% in 2020. [39]
5. $330 billion in annual hospital expenditures are paid by Medicare. [37]
6. ~1/2 the payments for physician services came from private health insurance between 2003 and 2007. [35]

7. ~$89 billion a year in 2006 and 2007 was the additional amount paid by private payers after calculating how much physicians and hospitals might be relying on private insurance pay to make up for lower federal rates. [49]
8. $6.8 billion was spent on clinical lab services by Medicare in 2007. [36]
9. 42%, 46%, and 38% are the shares of total clinical lab spending by hospital-based labs in 2007, 2006, and 1997, respectively. [36]
10. 1% was the decline in Medicare expenditures for all clinical lab services from 2006-2007 due to a drop in hospital-based lab spending (~9% increase per year between 1999 and 2006). [36]
11. >60% of all hip/knee implants and revisions are represented by Medicare, the single largest payer for hip & knee procedures. [38]
12. Private payers pay hospitals at a higher rate than Medicare and Medicaid. [49]



CMS average hospital payments for hip/knee procedures have enjoyed an upward momentum since early 2000 and have not been affected by the recent recession.

Insurance

Fast Fact:

Historically, health care (including orthopedics) has been recession resistant. The current recession appears to be different. People who are out of work and uninsured avoid visits to physicians.

1. 3.1% increase in health insurance premiums in 2008, the lowest rise since the 3.9% increase in 1967. [22]
2. 201 million people were covered by private insurance in 2008, a decrease from 202 million in 2007. [41]
3. ~46.3 million people were uninsured in 2008, an increase from 45.7 million in 2007, continuing to remain at 15.4% of the U.S. population. [41]
4. 58.5% was the percentage of people covered by employment-based health insurance in 2008, a decrease from 59.3% in 2007. [41]
5. ~80% of payments for physician services derived from private health insurance/public funds from 2003 to 2007. [35]
6. >60% of hospital surgeries have been performed in an outpatient setting since the late 1990s through 2005. [3]

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Musculoskeletal Clinical
Regulatory Advisers, LLC

Washington, DC
1331 H Street, NW 12th floor
Washington, DC 20005
Phone: 202.552.5800
Fax: 202.552.5798

New York, NY
505 Park Avenue, 14th floor
New York, NY 10022
Phone: 212.583.0250
Fax: 212.750.2112

Hartford, CT
63 East Center Street, 3rd Floor
West Manchester, CT 06040
Phone: 212.583.0250
Fax: 212.750.2112

info@mcra.com ***www.mcra.com***